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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,242	08/10/2001	Braj Bhushan Lohray	U 013593-6	5686

909 7590 07/07/2003

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,242	LOHRAY ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9,13,14,18,19,22-27,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9,13,14,22-27 and 36 is/are allowed.
- 6) ☒ Claim(s) 18 and 37 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This action is in response to Applicant's amendments filed May 8, 2003. Claims 1-9, 13, 14, 18, 19, 22-27, 36 and 37 are pending.

The 112 first paragraph rejection has been maintained and the 112 second paragraph rejection has been maintained. The claim objections have been overcome with Applicants amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

Claim 18 is directed to “a method of preventing diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

2) State of the prior art.

The prior arts do not indicate that the instant compound is useful in “preventing diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications”.

3) Level of ordinary skill in the art.

There are a vast number of diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications, and applicant does not give support for “preventing” all forms of these disorders. The level of ordinary skill in the art is high.

4) Level of predictability in the art.

The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. The art pertaining to diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications remains highly unpredictable.

5) Amount of direction and guidance provided by the inventor.

Applicant provides limited guidance regarding biological activity on pages 81-83. Applicant provides background information on pages 1-8.

6) Existence of working examples.

Applicant provides no working examples of how the instant compound is used.

7) Breadth of claims.

Claim 18 is extremely broad due to the large number of diseases encompassed by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

1) Nature of the invention

Claim 37 is directed to “converting a compound of formula (I)”, “resolving the racemic mixture into pure enantiomers by the known methods”, and “preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof”. The specification does not reasonably provide enablement for the instantly claimed process.

2) State of the prior art.

The prior arts do not indicate that the instant compound can be prepared by the process of claim 37.

3) Level of ordinary skill in the art.

The terms “converting a compound of formula of formula (I)”, “resolving the racemic mixture into pure enantiomers by the known methods”, and “preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof” may encompass a great number of processes. The level of ordinary skill in the art is high.

4) Level of predictability in the art.

The claims lack positive steps which teach how “converting a compound of formula (I)”, “resolving the racemic mixture into pure enantiomers by the known methods”, and “preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof” are performed. There is little predictability in the art of which modifications may be made to the processes as claimed in order to prepare the claimed compound.

5) Amount of direction and guidance provided by the inventor.

Guidance in preparing the instant compounds is provided on pages 28-36.

6) Existence of working examples.

Limited working examples are provided on pages 40-80.

7) Breadth of claims.

The claims are extremely broad because terms “converting a compound of formula (I) into a further compound of formula (I)”, “resolving the racemic mixture into pure enantiomers by the known methods”, and “preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof” may encompass a great number of processes.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The skilled artisan would have a numerous amount of modifications to perform in the processes as claimed order to obtain the claimed compound, therefore undue experimentation would be required to prepare instant compounds which are useful in the treatment of migraine.

These rejections can be overcome by Applicant deleting the term “or preventing” in claim 18, and listing positive process steps in claim 37.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is drawn to a process of converting a compound of formula (I) into a further compound of formula (I). It is unclear what is meant by the phrase "converting". For example, what is the compound of formula (I) converted to? How is the compound of formula (I) converted? Appropriate correction is requested.

Also, claim 37 contains the term "and/or" in step iv, which is confusing. It is unclear whether or not a pharmaceutically acceptable solvate is prepared with a pharmaceutically acceptable salt. It is suggested that Applicant delete "and/or" and insert "and optionally".

Claim Objections

Claim 19 is objected to as being dependent upon a rejected base claim.

Allowable Subject Matter

Claims 1-9, 13, 14, 22-27 and 36 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed May 8, 2003 have been fully considered but they are not persuasive with respect to claims 18 and 37. Applicant asserts that in order to expedite prosecution in this case to gain the earliest allowance to claims of present commercial interest, Applicant has deleted the term "preventing" in claim 18 and listed

positive process steps in claim 37. However, in the amendment filed by Applicants, the term “preventing” is still in claim 18. In claim 37, it is requested that Applicant provide detailed steps regarding how “converting”, “resolving”, and “preparing a pharmaceutically acceptable salt of compound of formula (1)” are performed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial

fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

July 1, 2003